

Serial Number: 10/625,792

Filing Date: 23 July 2003

Title: OPTICAL DISPLACEMENT SENSOR FOR INFUSION DEVICES

Assignee: DEKA Research & Development Corp.

REMARKS

As stated above, Applicants appreciate the Examiner's thorough examination of the subject application and respectfully request reexamination and reconsideration in view of the preceding amendments and the following remarks.

Currently, claims 1-6 and 8-20 are pending in this application, of which claims 1, 12, and 17 are independent. With this amendment, Applicants have amended independent claims 1, 12, and 17. Applicants respectfully submit that no new matter has been added as a result of these amendments.

The Examiner states new corrected drawings in compliance with 37 CFR 1.121 (d) are required in this application because the references in FIG. 1 to FIG. 4 have been manually written.

With this amendment, Applicants submit formal drawings in order to overcome the Examiner's rejection. However, Applicants note that formal drawings were previously submitted on August 27, 2003. In an effort to advance prosecution, Applicants are herein re-submitting these formal drawings in response to the Examiner's current rejection.

Claims 1-6 & 8-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (5,792,117) in view of Brown (6,113,578). Applicants respectfully traverse this rejection.

Applicants' newly amended independent claim 1 is provided below for the Examiner's convenience.

1. (Currently Amended) A displacement sensor for a medical fluid pump having a reservoir and a translating piston, the sensor comprising:
 - a. a plunger rod coupled to the piston bearing an encoded pattern of encoding features, wherein the encoding features include a plurality of slots, the spacing of

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- the encoding features from one another defining spaces between such that any two adjacent spaces form a unique sequence;
- b. a light source for illuminating the encoded pattern;
 - c. a detector array for detecting light from the illuminated encoded pattern and generating a detector signal, said detector array configured to detect at least two of said plurality of slots simultaneously; and
 - d. a processor for determining a displacement of the plunger rod relative to a fiducial reference position based at least on the detector signal. *Applicants' claim 1. (Emphasis added).*

Support for Applicants' newly amended independent claim 1 may be found throughout the subject application. For example, a description of the plurality of slots may be found in paragraphs [0020-0029] as well as in Figure 2 of the subject application. Paragraph [0020] is particularly illustrative of the plurality of slots of the subject application. This paragraph has been provided below for the Examiner's convenience.

[0020] In accordance with one embodiment of the invention, encoding features 46 are slots orthogonal to the axis of travel 32 of the piston are scored into plunger rod 38. In alternate embodiments, round (or otherwise shaped) holes, or slots parallel to axis 32, wedges, or other light-transmitting features may be employed, all the above provided solely for purposes of example and without limitation. Slots 46 or other optically transmissive features may be fully optically transmissive or may, alternatively, modulate the some detectable characteristic of light (designated by dashed lines 48) transmitted between source 42 and detector 44. Transmissive features 46 may thus employ filters (of neutral density or otherwise), thereby modulating the intensity and/or spectral characteristics of the transmitted light, or may employ polarizers or retardation plates, thereby modulating the polarization or phase of the transmitted light. All such techniques for encoding transmitted light are within the scope of the present invention as described herein and as claimed in any appended claims. *Subject application*, para. [0020].

In contrast, it is Applicants' understanding that Brown ('117) fails to teach or suggest each and every limitation of Applicants' newly amended claim 1. Specifically, Applicants are unable to find any reference to "a plunger rod coupled to the piston bearing an encoded pattern of encoding features, wherein the encoding features include a plurality of slots, the spacing of the encoding features from one another defining spaces between such that any two adjacent spaces form a unique sequence." Brown ('117) appears to teach the use of a plunger rod having color

markings on its outer surface. Applicants respectfully submit that this is far different than what Applicants have claimed.

Figure 1 of Brown ('117) is provided below for the Examiner's convenience.

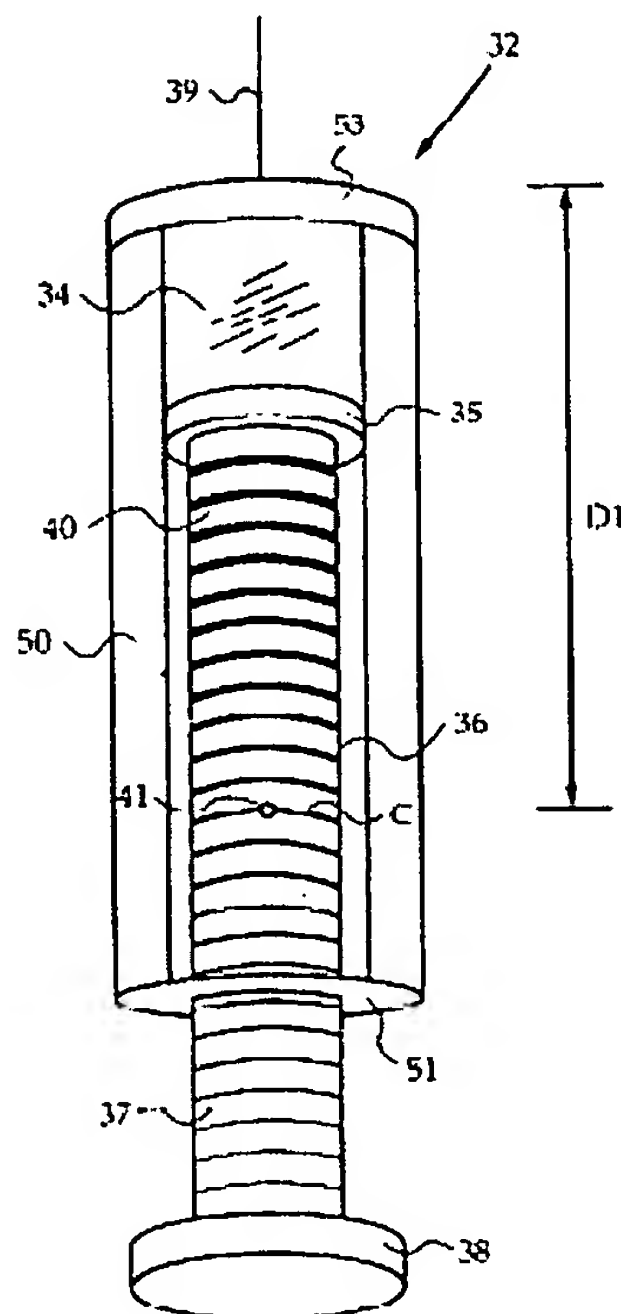


FIG. 1

It is Applicants' understanding that Brown appears to teach a plunger rod 37 "having a "variable color marking on its outer surface." *Brown*, col. 4, lines 12-13. Applicants note that the secondary reference cited by the Examiner, namely Brown ('578) is a related application, and as such includes a similar description of "variable color markings." *Brown* ('578), col. 8, lines 37-51. A more detailed discussion of the color markings of Brown ('117) is contained within

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column 4 of Brown ('117), portions of which have been provided below for the Examiner's convenience.

Plunger rod 37 has a variable color marking 40 on its outer surface. Variable color marking 40 extends along the outer surface of rod 37 from piston section 35 to cap 38. The color of marking 40 varies along the direction of the longitudinal axis of rod 37. In the preferred embodiment, the color of marking 40 varies in hue through the visible spectrum. In an alternative embodiment, the color of marking 40 varies in brightness from black to white. Marking 40 is preferably painted or dyed on rod 37. Alternatively, marking 40 may be painted or dyed onto a separate label which is then attached to rod 37. *Brown, col. 4, lines 12-22. Emphasis Added.*

Therefore, Applicants respectfully submit that Brown fails to teach or suggest each and every limitation of Applicants' newly amended claim 1. Namely, "a plunger rod coupled to the piston bearing an encoded pattern of encoding features, wherein the encoding features include a plurality of slots, the spacing of the encoding features from one another defining spaces between such that any two adjacent spaces form a unique sequence." As such, Applicants respectfully submit that newly amended independent claim 1 is in condition for allowance. Independent claims 12 and 17 have been amended to include similar limitations and are believed to be in condition for allowance as well.

Since the remaining dependent claims depend, either directly or indirectly, from Applicants' newly amended claims 1, 12, and 17, Applicants respectfully submit that these claims are in condition for allowance as well.

Moreover, Applicants' note that newly amended independent claim 1 is also patentable over Shearn (6,645,177), which was cited against the subject application in the non-final office action of June 26, 2007.

As discussed above, Applicants' newly amended claim 1 includes "a detector array for detecting light from the illuminated encoded pattern and generating a detector signal, said

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detector array configured to detect at least two of said plurality of slots simultaneously." Support for this amendment may be found, for example, in paragraph [0028] of the subject application, which has been provided below for the Examiner's convenience.

[0028] In a preferred embodiment of the invention, the spacing of plunger rod slots 46 is chosen in such a manner that any two adjacent spaces form a unique sequence. Additionally, the sum of the lengths of any two spaces is always greater than the distance between any two adjacent slots, thus, in case a slot becomes unintentionally blocked, the anomaly may be detected and not mistaken for another absolute position. Additionally, it is provided that either three or more slots are visible to the image sensor at any one time, or else the end of the rod and at least one slot are visible to the image sensor at any given time. *Subject Application, para. [0028]. Emphasis Added.*

As described in paragraph [0019] of the subject application the term "image sensor" refers to detector array 44. Additional support for this amendment may be found in paragraph [0031] of the subject application, which has also been provided for the Examiner's convenience.

[0031] In the embodiment to which Table I refers, there is a small portion of the travel where only two slots are visible (9 and 10) as well as the end of the rod. The normal means of identifying the syringe using two adjacent spaces cannot be used since only a single spacing is available. The alternate means of identifying the syringe using the distance between the end of rod and the last slot cannot be used because the end is too close to the edge of view to be detected using the sliding window algorithm. Thus a third means of identifying the syringe is used when only two slots are visible and the end of the rod position cannot be measured but is visible. This third method relies on a unique slot-9-to-slot-10 spacing. *Subject Application, para. [0031]. Emphasis Added.*

As described above, Applicants' newly amended independent claims 1, 12, and 17 include "a detector array for detecting light from the illuminated encoded pattern and generating a detector signal, said detector array configured to detect at least two of said plurality of slots simultaneously." Applicants respectfully submit that Shearn fails to teach or suggest this limitation.

Shearn generally discloses a syringe driver system having a "rotatable threaded lead screw shaft and a plunger which directly engages the threaded shaft such that rotation of the shaft drives the plunger into the syringe body." *Shearn, Abstract*. Figure 2 of Shearn depicts an exemplary embodiment of the syringe driver system of Shearn.

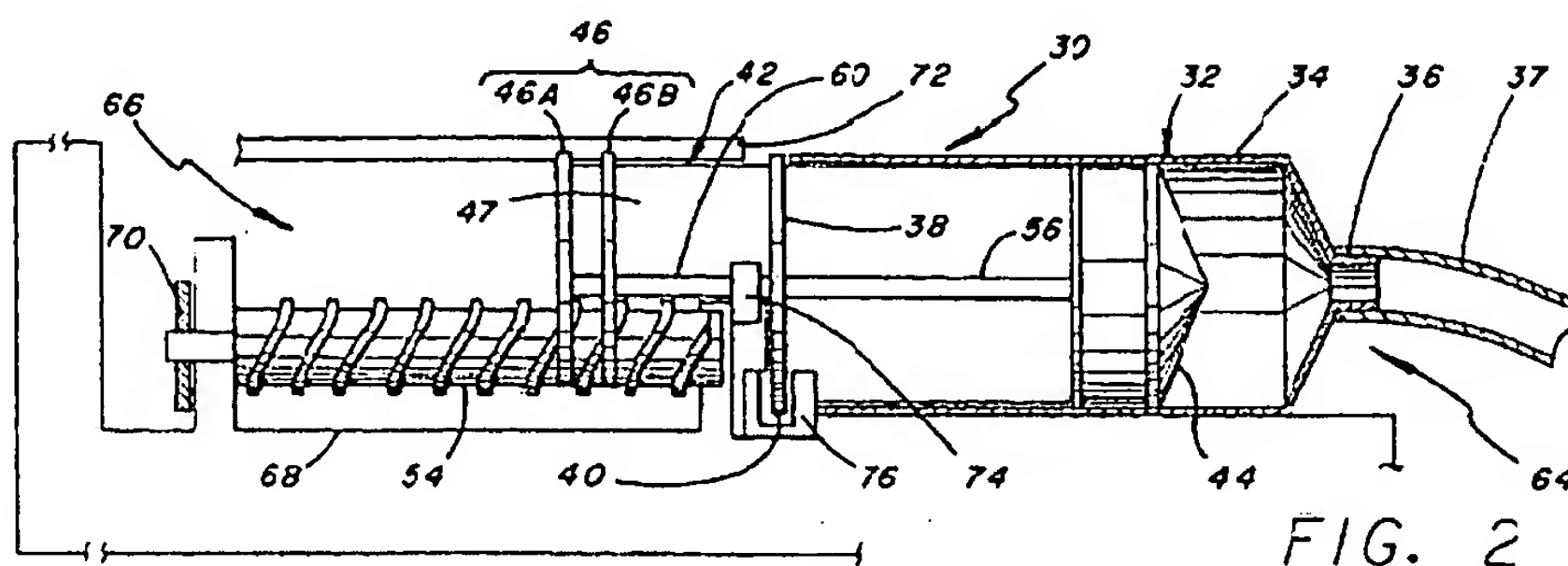


Figure 2 is described in Shearn in the following manner:

With continuing reference to FIG. 2, the casing 68 is provided with two opto-electronic detectors in this embodiment. The first detector 74 is used to provide detection of linear movement of the syringe plunger and a warning when the near-end-of-infusion (NEOI) point is being reached, i.e., when the syringe is almost empty and needs replacement. The detector 74 is mounted on the casing 68 adjacent the stem arm 56 upon which the markers 58, 60 (FIG. 6) are formed. The detector 74 is of substantially horse-shoe shape, one end of the horse shoe housing a light source and the other end of the horse shoe housing a pair of detectors located alongside one another such that light from the light source is blocked by the arm 56 so that neither of the detectors are illuminated but, when a marker 58 is positioned between the light source and the detectors, one of the detectors is illuminated. As the syringe plunger travels along the shaft 54, equally spaced dark and light signals are detected by the optoelectronics switch 74. The timing of these signals can be used by a control system to confirm that the plunger is moving at the correct rate. Similarly, a lack of detection of dark and light signals indicates to the syringe driver that no movement of the syringe plunger is occurring. This may be the result of an exhausted syringe, which means that the end of infusion ("EOI") has been reached, thus also providing detection of such condition. The processor of the syringe driver may be programmed to determine the EOI after first detecting the NEOI and to provide an audible and/or visual alarm or other indication of the EOI.

Since the markers at the NEOI point, which is at the proximal end **61**, are larger than the markers **58** along the rest of the length of the arm, the larger markers allow the light source of the NEOI detector to illuminate both detectors. This serves as an indication to a control system of the syringe driver that there has been a transition from the smaller markers at the distal end **60** to the larger markers at the proximal end **61** which means that the NEOI point

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is being approached and the syringe needs to be replaced. Such detection can trigger an alarm, provide a warning light or other form of indication. Clearly, the respective sizes of the markings can be reversed or the shapes or configurations can be changed to obtain the same effect and/or the transition or approach of the NEOI point can be encoded differently on the arm. *Shearn*, col. 8, lines 6-47. *Emphasis Added*.

Applicants respectfully submit that Shearn fails to teach or suggest "a detector array for detecting light from the illuminated encoded pattern and generating a detector signal, said detector array configured to detect at least two of said plurality of slots simultaneously." Upon reading the above passages, it is Applicants' understanding that Shearn teaches the passage of light through only one marker at a time. Specifically, and as noted in the highlighted sections above, Shearn states "when a marker 58 is positioned between the light source and the detectors, one of the detectors is illuminated" and "the larger markers allow the light source of the NEOI detector to illuminate both detectors." Applicants respectfully submit that Shearn fails to disclose a "detector array configured to detect at least two of said plurality of slots simultaneously." The discussion provided in Shearn appears only to teach the detection of light through one marker at a time. As such, Applicants respectfully submit that Applicants' newly amended claims are patentable over Shearn as well.

In light of the above-described amendments and remarks, applicants respectfully assert that the subject application is now in condition for allowance. No new matter has been added by these amendments. *While the applicants respectfully assert that the subject application is now in condition for allowance, the Examiner is invited to telephone applicants' attorney (@ 617-305-2143) to facilitate / expedite prosecution of this application.* Please apply any charges or credits to deposit account 50-2324.

REPLY TO FINAL OFFICE ACTION OF 25 MARCH 2008

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Respectfully Submitted,

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